II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Sterilmed, Inc.

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Date Prepared: 23 April 2012

Trade Name: Reprocessed Endoscopic Trocars

Classification Name: Endoscope and accessories

Classification Number: Class II, 21 CFR 876.1500

Product Code: NLM

Predicate Devices:	The reprocessed endoscopic trocars are substantially equivalent to Ethicon Endo-Surgery ENDOPATH® XCEL™ With OPTIVIEW® Technology Trocars (K032676).
Device Description:	The reprocessed endoscopic trocar is a sterile instrument consisting of a sleeve and obturator that is available in varying lengths and diameters. The obturator may be bladeless or dilating tip. Reprocessed trocars are devices that provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic, or other minimally invasive surgical procedures.
Intended Use:	The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures such as observation, dissecting, cutting, repairing, and removal or manipulation of internal tissues and/or organs.
Technological Characteristics:	The reprocessed endoscopic trocars are identical to the predicate devices in design, materials of construction (except for the absorbent ring which is non-patient contact), and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.
Functional and Safety Testing:	Representative samples of reprocessed endoscopic trocars were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed endoscopic trocar to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed endoscopic trocars are safe, effective, and substantially equivalent to the predicate devices, Ethicon Endo-Surgery ENDOPATH® XCEL™ With OPTIVIEW® Technology Trocars (K032676), as described in this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 1 1 2012

Sterilmed, Incorporated
c/o Mr. Jason Skramsted, RAC
11400 73rd Avenue, North
Maple Grove, Minnesota 55369

Re: K121240
Trade/Device Name: Reprocessed Endoscopic Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NLM
Dated: April 23, 2012
Received: April 24, 2012

Dear Mr. Skramsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Reprocessed Endoscopic Trocars

Indications for Use:

The reprocessed endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures such as observation, dissecting, cutting, repairing, and removal or manipulation of internal tissues and/or organs.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121240

K121240-List of device models included in this submission.

Manufacturer	Model #	Device Description
Ethicon Endo-Surgery	2B5ST	Bladeless Trocars (D 5mm, L 75mm, Stability Sleeve)
	2B5LT	Bladeless Trocars (D 5mm, L 100mm, Stability Sleeve)
	2D5ST	Dilating Tip Trocars (D 5mm, L 75mm, Stability Sleeve)
	2D5LT	Dilating Tip Trocars (D 5mm, L 100mm, Stability Sleeve)
	2CB5ST	Universal Sleeves (D 5mm, L 75mm, Stability Sleeve)
	2CB5LT	Universal Sleeves (D 5mm, L 100mm, Stability Sleeve)